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THE
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Cancer research news for clinicians

Non-Small Cell Lung Cancer

SBRT Delivers Higher Overall Survival Rates Compared to Conventional Radiation Therapy

Stereotactic body radiation therapy yielded higher overall survival rates and low toxicity for patients with inoperable, non-small cell lung cancer in comparison to conventional radiation therapy, according to a study.

The study evaluated the safety and efficacy of SBRT in 100 patients with medically inoperable NSCLC from June 2004 to November 2008, from 15 institutions throughout Japan with a median follow-up of 37 months.

Patients' overall survival rate was 59.9 percent after three years and only mild toxicity was shown.

(Continued to page 2)

Metastatic Melanoma

Abraxane Improves Progression-Free Survival Compared to Dacarbazine In Stage IV Disease

Abraxane improved progression-free survival in chemotherapy-naïve patients with stage IV metastatic melanoma compared dacarbazine chemotherapy, according to results from a phase III trial.

Patients receiving Abraxane (nanoparticle albumin-bound paclitaxel) demonstrated PFS of 4.8 months, compared to 2.5 months in patients receiving dacarbazine chemotherapy (HR:0.792; 95.1% CI: 0.631, 0.992; P=0.044).

An interim analysis of overall survival, the secondary endpoint, shows a trend in favor of the Abraxane arm—12.8 compared to 10.7 months (HR:0.831; 99.9% CI: 0.578, 1.196; P=0.094).

(Continued to page 3)

Glioblastoma

Phase III Trial of Avastin and Temozolomide Shows Reduced Risk of Cancer Progression

A phase III study of Avastin in combination with radiation and temozolomide chemotherapy demonstrated a reduced risk of cancer progression by 36 percent, compared to radiation, temozolomide and placebo in patients with newly diagnosed glioblastoma.

Progression-free and overall survival were the study's primary endpoints. Interim results for overall survival did not reach statistical significance. Final overall survival data from the study, named AVAglio, are expected in 2013.

(Continued to page 4)

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SBRT Can Extend Overall Survival Compared to Conventional RT

(Continued from page 1)

At the three-year follow-up, progression-free survival was 49.8 percent, local progression-free survival was 52.8 percent and event-free survival was 46.8 percent.

Of the grade 3 adverse events, 10 percent of patients experienced dyspnea, eight percent experienced hypoxia, seven percent experienced pneumonitis, two percent experienced chest pain and one percent experienced cough. Only two percent of patients experienced grade 4 events of dyspnea and hypoxia.

The research was presented at the American Society for Radiation Oncology's annual meeting. The study follows a 2010 report on operable patients with NSCLC.

At the start of the study, 77 male and 27 female patients ages 59-90 were included, with a median age of 78. Patients were treated with 48 Gy at the isocenter in four fractions for four to eight days.

Patients had a median tumor size of 21 mm (between 9 to 30 mm), with 50 patients exhibiting adenocarcinomas, 40 patients exhibiting squamous cell carcinomas and 14 with other types of lung cancer.

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Pancreatic Cancer

Abraxane and Gemcitabine Improves Overall Survival

Abraxane in combination with gemcitabine demonstrated a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone in a phase III study of patients with advanced pancreatic cancer.

In the MPACT trial, 861 treatment-naïve metastatic pancreatic cancer patients were randomized to receive either Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) plus gemcitabine (125 mg/m2 followed by 1000 mg/m2 gemcitabine for three weeks followed by a week of rest) or gemcitabine alone (1000 mg/m2 administered weekly for seven weeks followed by a week of rest followed by cycles of weekly administration for three weeks followed by one week of rest).

A late-breaker placeholder abstract for this study has been submitted to the American Society of Clinical Oncology's 2013 Gastrointestinal Cancers Symposium being held January 24-26, 2013.

Based on the results of the MPACT study, the company plans to submit dossiers for registration in the U.S., Europe and other markets.

Abraxane is not currently approved for the treatment of advanced pancreatic cancer. It is sponsored by Celgene International Sàrl, a subsidiary of Celgene Corp.

In the U.S., Abraxane was first approved in January 2005 for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy.

In October 2012, Abraxane was approved by the FDA for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

Metastatic Melanoma

Abraxane Improves PFS In Trial of Stage IV Patients

(Continued from page 1)

Abstracts of the randomized international study, named CA033, were published in the Society for Melanoma Research's official journal.

A majority of the patients were males (66 percent), had an ECOG status of 0 (71 percent), and had very advanced metastatic disease (M1c stage: 65 percent). Dacarbazine is the only chemotherapy approved since 1975 by the FDA for metastatic melanoma.

In the study, 529 chemotherapy-naïve patients were randomized to receive either Abraxane (150mg/m(2) weekly for three out of four weeks) (n=264) or standard chemotherapy, dacarbazine (1000 mg/m(2) every three weeks) (n=265).

The primary endpoint was progression-free survival based on blinded assessment of CT scans obtained every eight weeks, evaluated per RECIST. The secondary endpoint was OS and other endpoints included objective response rate, disease control rate, and safety and tolerability. Abraxane is a registered trademark of Celgene Corp.

Chemotherapy

Study Uncovers New Mechanism In Class of Chemotherapy Drugs

NCI researchers have discovered a significant new mechanism of action for a class of chemotherapy drugs known as poly (ADP-ribose) polymerase inhibitors, or PARP inhibitors. They have also identified differences in the toxic capabilities of three drugs in this class which are currently being tested in clinical trials.

Members of the PARP family of proteins are involved in a number of critical cellular processes, including DNA damage repair and programmed cell death. Prior to this study, PARP inhibitors were thought to work primarily by blocking PARP enzyme activity, thus preventing the repair of DNA damage and ultimately causing cell death.

In the study, published in Cancer Research, scientists established that PARP inhibitors have an additional mode of action: localizing PARP proteins at sites of DNA damage, which has relevance to their anti-tumor activity.

The trapped PARP protein-DNA complexes are highly toxic to cells because they block DNA replication. When the researchers tested three PARP inhibitors for their differential ability to trap PARP proteins on damaged DNA, they found that the trapping potency of the inhibitors varied widely.

"Critical to our research is that, while PARP inhibitors had been assumed to be of equivalent potency based on the degree to which they elicit PARP inhibition, we now know that they are not equivalent with respect to their potency to trap PARP," said Yves Pommier, of the NCI Center for Cancer Research. "Our findings suggest that PARP inhibitors should be categorized according to their potency to trap PARP, in addition to their enzyme inhibition abilities."

The PARP family of proteins in humans includes PARP1 and PARP2, which are DNA binding and repair proteins. When activated by DNA damage, these proteins recruit other proteins that do the actual work of repairing DNA. Under normal conditions, PARP1 and PARP2 are released from DNA once the repair process is underway. However, as this study shows, when they are bound to PARP inhibitors, PARP1 and PARP2 become trapped on DNA.

The researchers showed that trapped PARP-DNA complexes are more toxic to cells than the unrepaired single-strand DNA breaks that accumulate in the absence of PARP activity, indicating that PARP inhibitors act as PARP poisons.

Investigators used PARP assays to compare three PARP inhibitor compounds that are currently in clinical testing: MK-4827, olaparib, and veliparib.

The scientists found that the three PARP inhibitors differed in their ability to inhibit PARP enzyme activity, with olaparib being the most potent inhibitor, followed by veliparib and then MK-4827. However, in terms of toxicity, MK-4827 was the most potent, followed by olaparib and then veliparib. PARP1 complexes with MK-4827 and olaparib were shown to be more tightly bound to DNA than complexes with veliparib.

These findings suggest that there may be two classes of PARP inhibitors: catalytic inhibitors that act mainly to inhibit PARP enzyme activity and do not trap PARP proteins on DNA, and dual inhibitors that both block PARP enzyme activity and act as PARP poison.

"Our findings suggest that clinicians who use PARP inhibitors in clinical trials should carefully choose their drug, because we now suspect results may differ, depending upon the PARP inhibitor used," said Junko Murai, of the NCI Center for Cancer Research. "As a next step, we are working to categorize other leading PARP inhibitors based upon both PARP trapping and PARP inhibition."

The work was supported by the Intramural Program

of NCI and by the Japan Society for the Promotion of Science Core-to-Core Program.

Glioblastoma

Phase III Trial of Avastin Improves PFS by 4.4 Months

(Continued from page 1)

A 4.4 month improvement in median PFS was observed in patients receiving Avastin—10.6 months compared to 6.2 months in those receiving placebo. The 36 percent reduction in the risk progression or death can also be referred to as a 56 percent improvement in progression-free survival (HR=0.64; p<0.0001).

Secondary endpoints included progression-free survival as assessed by an independent review committee, one- and two-year survival rates, health-related quality of life measures, and safety profile. The one-year survival rate was 66 percent for the placebo arm versus 72 percent in the Avastin arm (p=0.052).

Avastin is currently approved in the U.S. under the FDA's accelerated approval program for glioblastoma that has progressed following prior therapy; it is approved for use as a single therapy and not in combination with other therapies. The effectiveness of Avastin is based on improvement in objective response rate. Currently, no data are available from randomized controlled trials demonstrating improvement in disease-related symptoms or increased survival with Avastin in glioblastoma.

AVAglio is the first positive phase III study in newly diagnosed glioblastoma since 2005. The data was presented at the annual meeting of the Society of Neuro-Oncology.

Breast Cancer

Adjuvant Radiation Treatment Shows Improved Survival In Elderly, Early-Stage Patients

Elderly women with early-stage breast cancer who received adjuvant radiation therapy after lumpectomy surgery have improved cause-specific survival compared to those patients who underwent surgery alone, according to a study.

Additionally, the data suggests that patients who have a life expectancy of at least 10 years after diagnosis and treatment benefit in local tumor control and in overall survival if they receive adjuvant radiation therapy.

The study, presented at the American Society for Radiation Oncology's annual meeting, evaluated the records of 29,949 women from the Surveillance, Epidemiology and End Results database between 1990 and 2008, ages 70 to 84, diagnosed with clinical stage I, estrogen receptor positive breast cancer who underwent lumpectomy with or without adjuvant radiotherapy and who survived at least one year after initial diagnosis.

Seventy six percent of the patients (n=22,781) received adjuvant radiation treatment. The median survival was 13.1 years for patients treated with surgery and radiation and 11.1 years for patients receiving surgery alone.

CSS after five years was statistically significant at 98.3 percent for patients who received adjuvant radiation treatment compared to 97.6 percent of patients who received surgery alone. After 10 years, CSS was 95.4 percent for patients who received adjuvant radiation compared to 94.3 percent of patients who received surgery alone.

At five, 10 and 15 years, the overall survival of patients was 89.5 percent, 66.8 percent and 40.8 percent, respectively, for those treated with surgery and radiation—compared to 83.0 percent, 56.1 percent and 30.2 percent for those treated with surgery alone.

As women aged, the use of radiation therapy decreased—accounting for 80 percent of women aged 70-74, 74 percent of women aged 75-79 and 61 percent of women aged 80-84.

This study furthered results of a previous Cancer and Leukemia Group B study that examined the addition of radiation to lumpectomy and tamoxifen in women age 70 and older with clinical stage I, ER+ breast cancer.

The CALGB study included 636 patients; 317 patients, or almost 50 percent, were treated with adjuvant radiation therapy. The study concluded an absolute reduction of six percent in ipsilateral breast tumor recurrence with the use of radiation at a median follow-up of 10.5 years, but there was no improvement in CSS or OS.

Lung Cancer Screening

Genetic Test Identifies Patients With High Risk of Mortality

New study data demonstrated the clinical utility of the Pervenio Lung RS genetic test and its ability to identify patients at high risk for mortality following surgery for early stage lung cancer.

The study reports new data from a subset of patients included in larger validation studies from earlier

this year. The test was initially validated through two independent, blinded retrospective studies involving approximately 1,500 patients, which were published in the March 2012 issue of The Lancet.

This study, published in the Journal of the American Medical Association, looks at patients with "T1a, node-negative" tumors, cancers that are smaller than two centimeters in diameter and that have no detectable spread of disease.

The test examines activity of 14 genes in tumor tissue. The study showed that the test accurately predicted mortality risk among 269 T1a, node-negative patients. The test categorized 92 patients as high risk; survival among these patients was just over 50 percent. Survival among patients classified by the test as low risk was nearly 85 percent.

Pervenio Lung RS is a product of Life Technologies Corp.

Whole Brain Radiotherapy

Memantine Can Delay Onset Of Cognitive Function Decline

Patients who received memantine during the course of whole brain radiotherapy for metastatic brain tumors experienced significant overall delay in the onset of cognition function decline.

Patients were 55 percent less likely to experience cognitive decline at six months after start of treatment than patients who received a placebo.

The phase III trial evaluated 508 patients with brain tumors who received WBRT between March 2008 and July 2010. In addition to cognitive function, the study analyzed the length of time before experiencing cognitive decline, overall survival and progression-free survival.

Patients received WBRT of 37.5 Gy in 15 fractions and were randomized to receive placebo or a 20mg dose of memantine per day within three days of initiating radiotherapy for 24 weeks.

Results showed that memantine delays cognitive decline in areas of recognition memory, global function, executive function and processing speed. The study data were presented at the 2012 American Society for Radiation Oncology annual meeting.

Patients in the memantine group experienced a 17 percent relative reduction in cognitive decline at 24 weeks compared to those in the placebo group. Patients' cognitive function as assessed utilizing the Controlled Oral Word Association test at eight and 16 weeks and the Trail Making Test Part A at 24 weeks also indicated fewer patients in the memantine group experienced decline.

Patients were also evaluated at 24 weeks with the Hopkins Verbal Learning Test-Revised Delayed Recall, which showed a median decline of 0 for patients who received memantine in comparison to those in the placebo group, who had a decline of -2.

The trends of all three cognitive tests for the 149 eligible patients who survived 24 weeks indicate that the memantine group yielded better results than the placebo at all points. There was no difference in patients' overall or progression-free survival between the treatment arms.

"Given the weight of the evidence comprised of multiple tests administered at multiple time points showing patients in the memantine arm had a delay in the onset of cognitive decline and a reduced rate of decline, we believe adults receiving whole brain radiotherapy should now receive this medication," said Nadia Laack, the trial's modality co-chair and assistant professor of radiation oncology at the Mayo Clinic.

"These practice-changing results have significant potential to improve the quality of life of the many patients living with metastatic brain cancer," said Walter Curran Jr., RTOG chair and executive director of the Winship Cancer Institute. "It is exciting to see this research come to fruition with widespread support of community cancer programs."

Head and Neck Cancer

Doxepin Rinse Reduces Pain In Radiation Therapy Patients

When used as a rinse, doxepin, a tricyclic antidepressant, reduces oral mucositis in patients who receive radiation therapy for head and neck cancer, according to research presented at the American Society for Radiation Oncology's annual meeting.

The double-blind, placebo-controlled phase III trial, with a cross-over phase, included 140 patients between December 2010 and May 2012 who received RT for their head and neck cancer (> 50.0 Gy) and which involved more than one-third of the oral cavity.

Throughout the study, patients completed a numerical, analog pain questionnaire to rate their OM pain on a scale of one to 10. The patients included in this study all reported OM pain scores above four prior to the study protocol to receive doxepin or placebo.

On the first day of the protocol, patients received a single, blinded dose of doxepin rinse or placebo and

then crossed over to the opposite study group on a subsequent day.

Results indicate that the addition of doxepin significantly decreased pain, which was measured by the area under the curve on the pain scale over time. Patients who received doxepin reported a reduction in pain to a -9.1 vs. -4.7 for those who received the placebo.

Analysis of the crossover data revealed similar findings, with an score of -7.9 in the doxepin group vs. -5.6 in the placebo group.

Doxepin was well tolerated, but patients reported increased stinging and burning with doxepin compared to the placebo (mean pain score of 3.7 for doxepin vs. 1.1 for placebo), unpleasant taste (mean unpleasant taste at five minutes of 2.9 for doxepin vs. 1.6 for placebo) and greater drowsiness (mean drowsiness score of 3.9 for doxepin vs. 2.8 for placebo). Sixty-four percent of patients elected to continue doxepin after the study was completed.

The study was conducted through the Alliance for Clinical Trials in Oncology, and patients received doxepin as an oralrinse and spit at a dosage of 25 mg in 5 ml water.

Drug Approvals

Zaltrap Receives Positive Opinion For European Market From CHMP

Zaltrap received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency.

The committee recommended granting a marketing authorization for Zaltrap (ziv-aflibercept) injection for intravenous infusion, in combination with FOLFIRI chemotherapy in adults with metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen. A final marketing decision is expected from the European Commission in the first quarter of 2013.

The CHMP opinion was based on data from the VELOUR trial. Zaltrap has been approved for the same indication in the U.S.

After a recent controversy over pricing, the company said it would offer rebates of 50 percent (The Cancer Letter, Nov. 2, Nov. 8, Nov. 16).

VELOUR was a phase III multinational, randomized, double-blind trial comparing FOLFIRI in combination with either Zaltrap or placebo in the treatment of patients with metastatic colorectal cancer.

Adding Zaltrap to FOLFIRI significantly improved median survival from 12.06 months to 13.50 months (HR=0.817 [95% CI 0.714 to 0.935]; p=0.0032), an 18 percent relative risk reduction. A significant improvement in progression-free survival from 4.67 months to 6.90 months (HR=0.758 [95% CI 0.661 to 0.869]; p=0.00007), a 24 percent relative risk reduction, was also observed.

The overall response rate in the Zaltrap plus FOLFIRI arm was 19.8 vs. 11.1 percent for FOLFIRI (p=0.0001).

The most common adverse reactions reported at a higher incidence in the Zaltrap-FOLFIRI arm were leucopenia, diarrhea, neutropenia, proteinuria, AST increased, stomatitis, fatigue, thrombocytopenia, ALT increased, hypertension, weight decreased, decreased appetite, epistaxis, abdominal pain, dysphonia, serum creatinine increased, and headache.

The most common Grade 3-4 adverse reactions were neutropenia, diarrhea, hypertension, leucopenia, stomatitis, fatigue, proteinuria, and asthenia.

Zaltrap is recombinant fusion protein that binds the angiogenic proteins VEGF-A, VEGF-B and placental growth factor. In the U.S., Zaltrap is a registered trademark of Regeneron Pharmaceuticals Inc.

In a related development, the European Commission approved Eylea (aflibercept) for the treatment of patients with neovascular (wet) age-related macular degeneration (wet AMD) on Nov. 27.

Eylea was approved for the treatment of neovascular (wet) AMD in the U.S. in November 2011.

Bayer HealthCare plans to launch Eylea in these countries later in 2012 and into 2013. In the United States, Eylea was also approved for the treatment of Macular Edema following Central Retinal Vein Occlusion in September 2012.

Bayer and Regeneron Pharmaceuticals are collaborating on the global development of Eylea and Regeneron maintains exclusive rights to Eylea in the U.S.

FDA granted a Fast Track designation to etirinotecan pegol (NKTR-102) for the treatment of patients with locally recurrent or metastatic breast cancer progressing after treatment with an anthracycline, a taxane, and capecitabine.

Etirinotecan pegol is a unique, targeted topoisomerase I inhibitor currently being evaluated in a phase III study, BEACON, in women with metastatic breast cancer.

The drug's sponsor, Nektar Therapeutics, requested the designation based upon the phase I and phase II clinical studies. Etirinotecan pegol was designed to improve the efficacy of irinotecan by modifying the distribution of the drug candidate within the body. Etirinotecan pegol has a non-overlapping mechanism of action with other agents used to treat breast cancer which may mitigate potential cancer cross-resistance and reduce overlapping toxicities.

The BEACON trial will enroll approximately 840 metastatic breast cancer patients who have had prior treatment with ATC in either the adjuvant or metastatic setting. The primary endpoint of the BEACON study is overall survival. Exploratory objectives of the study include collecting specific biomarker data which will be correlated with efficacy outcome measures. Enrollment in the BEACON study began in December 2011 and is expected to be completed by the end of 2013.

FDA granted orphan drug designations to amatuximab and the IMA901 cancer vaccine.

Amatuximab (MORAb-009) received an orphan designation for the treatment of malignant pleural mesothelioma.

Amatuximab is an investigational chimeric IgG1 antibody that targets a cell surface glycoprotein, mesothelin, which is over-expressed in a number of cancers. Mesothelin is thought to be involved in cell adhesion. Its presence is associated with a range of cancers, including pancreatic ductal adenocarcinoma, mesothelioma, epithelial ovarian cancer, and lung adenocarcinoma.

Amatuximab is sponsored by Morphotek Inc., a subsidiary of Eisai Inc.

FDA granted orphan drug designation to the IMA901 cancer vaccine for the treatment of renal cell carcinoma in HLA-A*02 positive patients.

The drug's sponsor, Immatics Biotechnologies GmbH, has completed patient recruitment to the phase III trial IMPRINT. The is designed to evaluate overall survival benefit with IMA901 in combination with sunitinib (Sutent), standard first-line therapy in comparison to sunitinib alone in patients with metastatic and/or locally advanced renal cell carcinoma. Interim overall survival results are expected during the first half of 2014.

FDA granted priority review to Stivarga tablets for patients with metastatic and/or unresectable gastrointestinal stromal tumors that has progressed despite prior treatment with two kinase inhibitors.

This priority review follows the recent FDA approval of Stivarga (regorafenib) for the treatment of patients with metastatic colorectal cancer.

The submission was based upon data from the global phase III GRID study. Stivarga was developed by Bayer HealthCare and is jointly promoted by Bayer and Onyx Pharmaceuticals.

Stivarga is an oral multi-kinase inhibitor that inhibits several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis. It also inhibits various oncogenic and tumor microenvironment kinases including KIT, RET, PDGFR, and FGFR.

The European Commission designated HyperAcute-Pancreas Immunotherapy as well as liposomal daunorubicin as orphan medicinal products, following positive opinions from the Committee for Orphan Medicinal Products.

HyperAcute-Pancreas Immunotherapy (algenpantucel-L) is currently being studied in IMPRESS, a phase III clinical trial of approximately 700 stage I and stage II surgically-resected pancreatic cancer patients.

The trial is being performed under a Special Protocol Assessment with the FDA. Currently, algenpantucel-L has both orphan drug designation and fast track status in the U.S.

Algenpantucel-L consists of a group of two allogeneic pancreatic cancer tumor cell lines that were genetically modified to express Alpha-Gal. These cell lines were chosen to provide a broad coverage of pancreatic cancer antigens. Algenpantucel-L is sponsored by NewLink Genetics Corp.

Liposomal daunorubicin received an orphan medicinal product designation for the treatment of acute myeloid leukemia.

Liposomal daunorubicin is an anthracycline chemotherapy agent currently approved in a number of European countries, the U.S., and Brazil for the treatment of advanced HIV-related Kaposi's sarcoma, as DaunoXome. It is sponsored by Galen Pharmaceuticals Ltd.

NCI-Approved CTEP Trials For the Month of November

The National Cancer Institute Cancer Therapy Evaluation Program approved the following clinical research studies last month. For further information, contact the principal investigator listed.

Phase I

ADVL1111: A Phase 1 Study of the c-Met Inhibitor, Tivantinib (ARQ 197, IND# 112603) in Children with Relapsed or Refractory Solid Tumors. COG Phase 1 Consortium; Geller, James Ian. (513) 636-6312

CITN11-02: A Phase 1 Study of Recombinant Human IL15 (rhIL15) in Adults with Advanced Solid Tumors: Melanoma, Renal Cell, Non-Small Cell Lung and Head and Neck Cancer. Cancer Immunotherapy Trials Network; Miller, Jeffrey Steven. (612) 625-7409

NANT N2011-04: A Phase I Study of Lenalidomide and Anti-GD2 Mab Ch14.18 +/- Isotretinoin in Patients with Refractory/Recurrent Neuroblastoma. New Approaches to Neuroblastoma Therapy (NANT); Marachelian, Araz. (323) 361-5687

Phase I/II

A091101: TPF Induction Chemotherapy and ABT-888 (Veliparib) - a Phase 1/Randomized Phase 2 Study in Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck. Cancer and Leukemia Group B; De Souza, Jonas. (773) 834-1736

Phase II

9144: A Phase II Study of Bevacizumab Alone or in Combination with TRC 105 for Advanced Renal Cell Cancer. City of Hope; Dorff, Tanya Barauskas. (323) 865-3900

E2211: A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors. Eastern Cooperative Oncology Group; Kunz, Pamela L. (650) 725-9057

GOG-0186K: A Randomized Phase II Study of NCI Supplied Cabozantinib (NSC #761968 IND #116059) Versus Weekly Paclitaxel (NSC #673089) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. Gynecologic Oncology Group; Matulonis, Ursula Anne. (617) 632-2334

Phase III

A011104: Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of women with Breast Cancer. Cancer and Leukemia Group B; Bedrosian, Isabelle. (713) 563-1872

A221101: A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil) To Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiform. Cancer and Leukemia Group B; Umphrey, Alyx B. Porter. 507-266-5230

RTOG-1112: Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma. Radiation Therapy Oncology Group; Dawson, Laura Ann. (416) 946-2125

Other Phases

EL912T3: Telomere Length, Type and Presence of TERT/TERC Mutations and Clinical Outcomes in Patients with Acute Promyelocytic Leukemia (APL). Eastern Cooperative Oncology Group; Baljevic, Muhamed. (917) 913-9166

SCUSF-1102: A Cluster Randomized Contolled Intervention Trial to Promote Standard of Care for Genetic Counseling Referral of Patients with Breast Cancer. SunCoast CCOP Research Base at the University of South Florida; Sutphen, Rebecca. (813) 396-9224